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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/671,070	09/24/2003	Rama Bhatt	200144.404	5866

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EXAMINER

RAO, DEEPAK R

ART UNIT PAPER NUMBER

1624

DATE MAILED: 06/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/671,070	BHATT ET AL.	
	Examiner	Art Unit	
	Deepak Rao	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-59 are pending in the application.
- 4a) Of the above claim(s) 19-59 are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>20040126</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-59 are pending in this application.

Election/Restrictions

Applicant's election of Group I, claims 1-18 in the reply filed on January 4, 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-18 (in part, drawn to compounds wherein Q is chalcogen or chalcogen containing group) and claims 19-59 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on January 4, 2006.

Note: The examiner in the previous office action has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

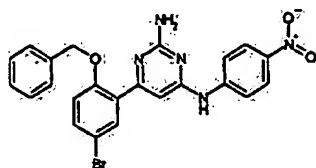
In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b),"

Art Unit: 1624

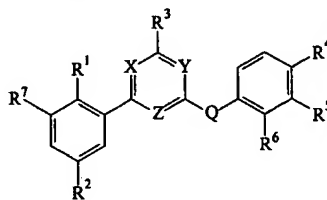
1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant's election of the species of Compound 177 is also acknowledged. The elected species is depicted below for convenience:



The species represents a compound of formula:



wherein:

X and Y are N, Z is CH;

Q is NH;

R¹ is Phenyl-CH₂-O-;

R² is Br;

R³ is NH₂;

R⁴ is N⁺(=O)O⁻; and

R⁵, R⁶ and R⁷ are H.

The elected species reads on claims 1-3, 5-12 and 14-18.

Art Unit: 1624

Applicant is reminded of the election of species guidelines provided in MPEP § 803.02, which are followed for examination. Portion from MPEP is provided here for convenience:

As an example, in the case of an application with a Markush-type claim drawn to the compound $\text{*} > \text{X-R} <$, wherein R is a radical selected from the group consisting of A, B, C, D, and E, the examiner may require a provisional election of a single species, $\text{*} > \text{XA}$, XB, XC, XD, or XE<. The Markush-type claim would then be examined fully with respect to the elected species and any species considered to be clearly unpatentable over the elected species. If on examination the elected species is found to be anticipated or rendered obvious by prior art, the Markush-type claim and claims to the elected species shall be rejected, and claims to the nonelected species would be held withdrawn from further consideration. $\text{*} > \text{A} <$ second action on the rejected claims $\text{*} > \text{can} <$ be made final unless the examiner introduces a new ground of rejection that is neither necessitated by applicant's amendment of the claims nor based on information submitted in an information disclosure statement filed during the period set forth in 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p). See MPEP § 706.07(a)<.

On the other hand, should no prior art be found that anticipates or renders obvious the elected species, the search of the Markush-type claim will be extended. If prior art is then found that anticipates or renders obvious the Markush-type claim with respect to a nonelected species, the Markush-type claim shall be rejected and claims to the nonelected species held withdrawn from further consideration. The prior art search, however, will not be extended unnecessarily to cover all nonelected species. Should applicant, in response to this rejection of the Markush-type claim, overcome the rejection, as by amending the Markush-type claim to exclude the species anticipated or rendered obvious by the prior art, the amended Markush-type claim will be reexamined. The prior art search will be extended to the extent necessary to determine patentability of the Markush-type claim. In the event prior art is found during the reexamination that anticipates or renders obvious the amended Markush-type claim, the claim will be rejected and the action $\text{*} > \text{can be} <$ made final unless the examiner introduces a new ground of rejection that is neither necessitated by applicant's amendment of the claims nor based on information submitted in an information disclosure statement filed during the period set forth in 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p). See MPEP § 706.07(a)<. Amendments submitted after the final rejection further restricting the scope of the claim may be denied entry $\text{*} > \text{if they do not comply with the requirements of 37 CFR 1.116. See MPEP § 714.13.}$

Based on the guidelines above, the prior art search was conducted to the extent of the compounds of formula (recited in claim 1) wherein X and Y are N, Z is CH or CR; Q is NH; R³ is NH₂; and R, R¹, R², R⁴, R⁵, R⁶ and R⁷ are as defined in the claims, and art was found. Claims 1-18 read on the expanded subgenus. All other definitions of the variables from the generic claims are held withdrawn from consideration, pursuant to 37 CFR 1.142(b) and the guidelines of MPEP 803.02, as being drawn to non elected subject matter.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

1. In claim 1, in the definitions of the variables (e.g., R^3 - R^6), the term “acyl” is confusing based on the definition provided in the specification. The specification on page 8, lines 4-14, defines that ‘the ‘acyl’ group refers to C(O)-R” wherein R” is selected from hydrogen, hydroxyl, substituted amino groups,alkoxy, etc.’ and therefore, the term ‘acyl’ includes carboxy, esters, amides, etc. which goes beyond the conventional meaning of the term ‘acyl’. ‘Acyl’ is generally known as a functional group obtained from an acid (e.g., a carboxylic acid) by removal of the hydroxyl group, represented by the formula RC(O)- wherein R denotes the group that occurs in the original carboxylic acid (see <http://en.wikipedia.org/wiki/Acyl>). The inclusion of the groups hydroxyl, amino, alkoxy etc. as the R group in the definition of ‘acyl’ is outside of the scope of the conventionally known definition of the term. Claim 8 (dependent on claim 1) recites the term C(=O)R for the variables R^4 and R^5 and some of the compounds in Table 1 have the group -C(=O)-OCH₃ as the R^4 group (see compound 9) which do not fall within the meaning of ‘acyl’.
2. Claims 9 and 18 refer to “compounds 1-192 of Table 1” without actually providing what these ‘compounds’ are. The claim must include all the limitations within the claim. See

Art Unit: 1624

MPEP § 2173.05(s). Reference to Figures or Tables: Where possible, claims are to be complete in themselves. Incorporation by reference to a specific figure or table "is permitted only in exceptional circumstances where there is no practical way to define the invention in words and where it is more concise to incorporate by reference than duplicating a drawing or table into the claim. Incorporation by reference is a necessity doctrine, not for applicant's convenience." *Ex parte Fressola*, 27 USPQ2d 1608, 1609 (Bd. Pat. App. & Inter. 1993) (citations omitted).

3. Claims 9 and 18 recite the "compounds 1-192 of Table 1" in line 2. There is insufficient antecedent basis for some of the compounds (as depicted in Table 1, see e.g., the compound 177) in claim 1 on which the claims are dependent. Compound no. 177 contains a benzyloxy group (i.e., -O-CH₂-Phenyl) as the R¹ substituent. The definition of R¹, however, does not include such a group. Similarly, compound 149 contains a -O-(CH₂)₂-morpholino group as the R¹ substituent and claim 1 does not provide for such group under the definition of R¹. (Similar structural discrepancy exists between other species of claims 9 and 18, only representative compounds are discussed here to show the discrepancy between the generic claims and the species included in these claims). Claim 1 does not specifically recite the groups provided under R¹ are further substituted.

Claim Rejections - 35 USC § 102

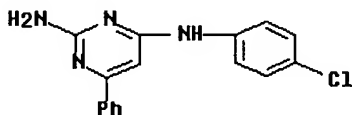
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

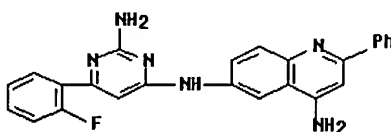
Art Unit: 1624

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-3, 5, 7-12, 14, and 16-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Hitchings et al., U.S. Patent No. 2,691,655. The instantly claimed compounds read on reference disclosed compounds, see the compounds of structural formula of col. 1, lines 15-18, and the corresponding species of Examples 7-9, etc. (The structural formula of the compound of Example 8 is depicted below for convenience, which is identical to the compound No. 106 of Table 1, page 126).



2. Claims 1-3, 5-7, 10-12, and 14-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Chaudhari et al., WO 02/36586. The instant claims read on reference disclosed compounds, see the compounds disclosed in Table 1, pages 34-46. (The structural formula of Ex # 3 from the table is depicted below for convenience).



Claim Rejections - 35 USC § 103

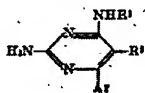
The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

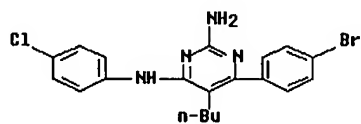
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 1624

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3, 5-12, and 14-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hitchings et al., U.S. Patent No. 2,691,655. The reference teaches a generic group of

compounds represented by the formula:  and the corresponding species disclosed in the examples. The compounds are taught to be useful as medicinal agents, see col. 1, first paragraph. Claims 1-3, 5, 7-12, 14, and 16-18 read on reference compounds. The compound according to claim 6 or 15 requires that the 3-position substituent on the phenyl ring (R^2) is Cl or Br. The reference discloses a compound of Example 15 (structure depicted below for convenience):



wherein a bromo is at the 4-position. The instant claims differ from the reference compound by reciting that the 3-position substituent is Br and therefore, the instantly claimed compounds are positional isomers of the reference compounds. It would have been obvious to one having ordinary skill in the art at the time of the invention to prepare the instantly claimed compounds

Art Unit: 1624

because they are positional isomers of the reference compounds. One having ordinary skill in the art would have been motivated to prepare the instantly claimed compounds because such isomeric compounds are suggestive of one another and would be expected to share similar properties and therefore, the same use as taught for the reference compounds, i.e., as pharmaceutical agents. It has been held that a compound, which is structurally isomeric with a compound of prior art is prima facie obvious absent unexpected results. *In re Finley*, 81 USPQ 383 (CCPA 1949); *In re Norris*, 84 USPQ 458 (CCPA 1950); *In re Dillon*, 919 F.2d at 696, 16 USPQ2d at 1904 (Fed. Cir. 1990).

Receipt is acknowledged of the Information Disclosure Statement filed on January 26, 2004 and a copy is enclosed herewith.

Conclusion


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deepak Rao whose telephone number is (571) 272-0672. The examiner can normally be reached on Tuesday-Friday from 6:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, can be reached at (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Art Unit: 1624

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Deepak Rao
Primary Examiner
Art Unit 1624

June 20, 2006